

REMARKS/ARGUMENTS

Claims 38-43 and 45-47 are pending.

Claims 38-43 and 45-47 were examined and rejected.

The claims are not amended. The Applicants request reconsideration of this application in view of the remarks set forth below.

Interview Summary

Examiner Rao is thanked for the productive telephone interview with the Applicants' representative, James Keddie, on June 7, 2007.

Outstanding rejections and arguments to overcome those rejections were discussed.

The Examiner agreed to re-reconsider the outstanding rejections in view of the Applicants' arguments.

Rejection of claims under 35 U.S.C. § 102

Claims 38-40 and 42 are rejected under 35 U.S.C. 102(e) as being allegedly anticipated by *Daly* (US20020037582). The Applicants respectfully traverse this rejection.

The claims recite a cell-free composition that contains an isolated Tankyrase H protein that exhibits poly-ADP ribose polymerase activity, *and* a source of ADP ribose.

The Applicants submit that *Daly* fails to disclose such a composition for two reasons.

Firstly, since *Daly*'s cell extracts can be made by lysing cells under denaturing conditions (e.g., by boiling the cells or by lysing the cells in a buffer that contains chemical denaturants), *Daly*'s cell extracts do not necessarily contain enzymatically active Tankyrase H protein, as required by the claims. As such, the Applicants believe that this rejection cannot be supported by a theory of inherency, which requires that an element be *necessarily* present in a reference.¹

¹ See MPEP § 2112: "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic."¹ (emphasis in the original). Accordingly, in order for such rejection to be correctly established, according to the MPEP, a claim limitation that is not explicitly taught must be inherent, i.e., necessarily present, in the cited prior art. The mere possibility that the limitation is taught in the art is not sufficient to merit such a rejection, and the mere fact that a certain thing *may* result from a given set of circumstances is also not sufficient.

Secondly, the instant claims are directed to a composition that requires *both* an isolated Tankyrase H protein and a source of ADP-ribose. As discussed during the aforementioned interview, the Applicants believe that upon isolation of Tankyrase H from the components of a cell, the protein becomes separated from the source of ADP-ribose. As such, Daly's Tankyrase H-containing compositions contain either: a) Tankyrase H protein in the absence of a source of ADP-ribose (e.g., the "purified protein" described in ¶14 on page 2 contains protein but no source of ADP-ribose); or b) *non-isolated* Tankyrase H protein in the presence of a source of ADP-ribose (e.g., in the case of the cell lysate of ¶23).

During the interview, the Examiner noted that this rejection was based on a broad interpretation of the word "isolated" in the phrase "isolated Tankyrase H protein" in claim 38.

According to MPEP § 2173², however, claim terms should be evaluated in view of teachings of the specification, teachings of the prior art, and how the claim would be read by one of ordinary skill in the art. Per MPEP § 2173.02, the meaning of claim terms should *not* be evaluated in a vacuum.

The Applicants submit that given the art-recognized meaning of the term "isolated" and the discussion of what is meant by the term "isolated" on page 15 of the instant specification, one of skill in the art would not read the instant claims as including a lysate of cells (i.e., cells that are broken open). To the contrary, given the art-recognized meaning and the instant specification, one of skill in the art would understand that a cell lysate such as that described in ¶23 of Daly contains *non-isolated* Tankyrase H protein. This is *not* the composition that is being claimed.

As such, the Applicants believe that Daly does not anticipate the claims, and this rejection should be withdrawn.

Withdrawal of this rejection is respectfully requested.

Rejection of claims under 35 U.S.C. § 103

Claims 41 and 43-44 are rejected under 35 U.S.C. 103 as being unpatentable over *Daly* in view of *Smith*. The Applicants respectfully traverse this rejection.

² See, e.g., MPEP § 2173.02: "Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The content of the particular application disclosure;
(B) The teachings of the prior art; and
(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made."

The Applicants submit that *Smith* fails to meet *Daly*'s deficiency and, as such, Daly and Smith, taken in any combination, fail to teach or suggest all of the elements of the rejected claims.

The Applicants submit that these rejections have been adequately addressed. Withdrawal of these rejections is respectfully requested.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number RIGL-010CIP3.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

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By: 

James Keddie
Registration No. 48,920

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, California 94303
Telephone: (650) 327-3400
Facsimile: (650) 327-3231